



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/644,388

08/19/2003

Robert A. VanTassel

4055

6130

21834 7590 01/23/2008
BECK AND TYSVER P.L.L.C.
2900 THOMAS AVENUE SOUTH
SUITE 100
MINNEAPOLIS, MN 55416

EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

01/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/644,388

Applicant(s)

VANTASSEL ET AL.

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 3-7 and 22-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2 and 8-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 3763

DETAILED ACTION***Response to Amendment***

Examiner acknowledges the amendment filed 10/31/2007 in which claim 1 was amended and new claims 16-27 were added. Currently claims 1-27 are pending for examination, with claims 3-7 and 22-27 are withdrawn from a previous office action and the current action. The terminal disclaimer filed 10/31/2007 was not approved because the attorney that signed is not of record in the file, therefore the double patenting rejections are maintained.

Election/Restrictions

Newly submitted claims 22-27 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The method claims are patentably distinct because they are drawn to a specific treatment area and the steps of implantation.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22-27 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

Art Unit: 3763

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,2 and 8-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-39 of U.S. Patent No. 6,949,113 and claims 1-9 of U.S. Patent No. 6,652,556. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the current pending application are anticipated by the claims in the cited US patent.

Application claim 1 requires:

Apparatus for permanent placement across an ostium of a left atrial appendage in a patient, comprising: a filtering membrane configured to extend across the ostium of the left atrial appendage and having a permeable structure which allows blood to flow through the filtering membrane but substantially inhibits thrombus from passing therethrough; and a support structure defining a first configuration having a substantially cylindrical shape and a second configuration defining a radially enlarged medial portion to permanently engage the interior wall of the left atrial appendage, wherein the filtering

Art Unit: 3763

membrane is attached to the support structure extending across the ostium of the left atrial appendage.

While patent (6,949,113) claim 22 requires:

A membrane structure for obstructing an opening in the body of a patient, said membrane comprising: a membrane adapted to be lodged against the opening; prongs adjacent an edge of the membrane extending substantially outwardly for attaching the membrane to body tissue on the opposite side of the opening from the membrane substantially adjacent the opening for securing the membrane over the opening; and a catheter for minimally invasively inserting the membrane over the opening to block the opening.

While patent (6,652,556) claim 1 requires:

Apparatus for permanent placement across an ostium of a left atrial appendage in a patient, comprising: a filtering membrane configured to extend across the ostium of the left atrial appendage and having a permeable structure which allows blood to flow through the filtering membrane but substantially inhibits thrombus from passing therethrough; and a support structure defining a first configuration having a substantially cylindrical shape and a second configuration defining a radially enlarged medial portion to permanently engage the interior wall of the left atrial appendage, wherein the filtering membrane is attached to the support structure extending across the ostium of the left atrial appendage, wherein the filtering membrane has a composite construction comprising a filtering section and an elastic section, and wherein the elastic

section has an opening to accommodate an intervention device.

Thus it is apparent that the application claims are broader than the patent claims and the subsequent patented independent and dependant claims encompass application claims 1, 2 and 8-15. Following the rationale in *In Re Goodman* cited in the preceding paragraph, where Applicant has once been granted a patent containing a claim for the specific or narrower invention, Applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting a terminal disclaimer.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 8, 10-13, and 15-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Cottenceau et al. (5,375,612). Cottenceau et al. discloses a blood filter.

Regarding claims 1, 2, 8, 10-13 and 15, Cottenceau et al. discloses an apparatus (Figure 1) for permanent placement across an ostium of a left atrial appendage in a patient comprising, a filtering membrane (9) configured to extend across the ostium of the left atrial appendage and having a permeable structure which allows blood to flow through the filtering membrane but substantially inhibits thrombus from passing therethrough, and a support structure (7, 15) defining a first substantially cylindrical shape to a second radial configuration (Figures 13-15) wherein the filtering membrane

(9) is attached to the support structure (7, 15) and is capable of crossing the ostium of the left atrial appendage. Cottenceau et al. further discloses a plurality of fingers with barbs (19) (Figures 1-4) (near 7) with first, second and medial portion, that expand radially outward with barbed outer members (19, see Figure 2) and are fabricated of stainless (col 4, ln 30-40). Cottenceau et al. discloses a delivery actuation device (43, 45) configured to remotely radially expand the support structure (See Figures 13-15).

Claim Rejections - 35 USC § 102

Claims 1 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Mobin-Uddin (3,540,431). Mobin-Udden discloses a collapsible filter assembly.

Regarding claims 1 and 16, Mobin-Udden discloses an apparatus (Figure 4) for permanent placement across an ostium of a left atrial appendage in a patient comprising, a filtering membrane (30) configured to extend across the ostium of the left atrial appendage and having a permeable structure which allows blood to flow through the filtering membrane but substantially inhibits thrombus from passing therethrough, and a support structure (116, 26, 50) made of a shape memory material defining a first substantially cylindrical shape to a second radial configuration (Figure 3) wherein the filtering membrane (30) is attached to the support structure (7, 15) and is capable of crossing the ostium of the left atrial appendage (Figures 1-6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 3763

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9 and 14 are rejected under 35 U.S.C 103(a) as being unpatentable over Cottenceau et al.

Regarding claims 9 and 14, Cottenceau et al. discloses the claimed invention except for the support structure being composed of nitinol or a shape memory material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the materials as claimed by Applicant in order to achieve proper expansion and delivery inside the patient, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Response to Arguments

Applicant's arguments filed 10/31/2007 have been fully considered but they are not persuasive. Applicant's representative asserts that the Cottenceau et al. (5,375,612) reference does not disclose a permanent support frame that exhibits shape memory characteristics. Examiner has fully considered applicant's arguments but they

Art Unit: 3763

are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that Applicant has not addressed the 102(b) rejection under Mobin-Uddin (3,540,431) of claim 1 which is now extended to new claim 16.

Additionally, the devices of both are made of Phynox and/or eligoy which are both well known alloy materials that are comparable equivalents to nitinol and capable of having shape memory characteristic depending on the methods of fabrication and cold working. Additionally, the Cottenceau et al. (5,375,612) reference discloses a bioabsorbable embodiment and non-bioabsorbable permanent (col 4, ln 40-60) embodiment, and thus meets the "permanent" limitation which Examiner interprets as lasting long enough to complete a treatment task.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

Art Unit: 3763

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

1/18/08


Christopher D. Koharski
AU 3763